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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,404	01/26/2005	Takeshi Imamura	03500.017461.	5542
5514 7590 09/05/2008 FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK, NY 10112				
EXAMINER LEVKOVICH, NATALIA A				
ART UNIT 1797		PAPER NUMBER		
MAIL DATE 09/05/2008		DELIVERY MODE PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/522,404

**Applicant(s)**

IMAMURA ET AL.

**Examiner**

NATALIA LEVKOVICH

**Art Unit**

1797

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6, 9, 10 and 12-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 9, 10 and 12-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/23/2008 has been entered.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-4, 6, 9-10 and 12-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1 and 12 recite a liquid transfer apparatus having a plurality of units, wherein each unit "can be connected to and disconnected from the liquid transfer

apparatus like a cassette". Upon further reviewing of the original specification, Examiner found no support for this limitation. The specification states that "each liquid transfer apparatus is realized as an *independent unit that is like a cassette* and can be connected to and disconnected from other liquid transfer apparatuses". In other words, the specification supports modularity of the liquid transfer apparatus. However, nowhere the specification states that the units *are connected "like a cassette"*, that is, configured for being inserted into, or ejected from a common housing, or support.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-4, 6, 9-10 and 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being unclear for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular, claims 1 and 12 recite a liquid transfer apparatus having a plurality of units, wherein each unit "can be connected to and disconnected from the liquid transfer apparatus like a cassette". It is unclear whether or not any common support structure / housing is intended. It is also unclear whether being connected "like a cassette" implies some limitations to the shape of a unit. Additionally, it is not clear what structural elements would limit the volumes of the transferred liquids to micro-volumes.

#### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3, 9-10 and 12-14 are rejected under 35 U.S.C. 102(b) as anticipated by Neukermans (US 6068751).

Neukermans discloses a modular fluidic delivery system comprising, as shown in Figures 1, 2, 10a and 10, module 20, 100 which includes component 32, 128 with capillary 62, 126 [liquid containing section] having inlet [liquid introducing section] and outlet [liquid leading out section]. The capillary is provided with piezo-electric actuator 34 [energy application means] configured for ejecting micro-volumes of fluids out of the capillary. The module is shaped like a cassette and can be connected to other modules, in parallel or in series, to form more complex fluidic circuits: "[T]he liquid delivery system can be used as a component in assembling much more complex microfluidic systems which also form part of the present invention" (see Figures 10a, 10; Col.3, lines 35-40). In particular, Figure 10 shows components 128 being connected serially, that is, the outlet ['liquid leading out section'] of one ['second'] component 128 is fluidically connected to the liquid introducing section of another ['first'] component 128, the two components being configured for transferring micro-volumes of liquid from one to the other.

Regarding claim 2, Neukermans discloses self-sealing material in inlets 158 in column 10, lines 25-30.

Referring to claim 3, pouch 122 used as a reaction camera is provided with heater 152 [processing means] (see Figure 3).

With respect to claims 9-10, Neukermans describes integrating a variety of detectors into the fluidic system (see Col. 14, lines 1 plus).

Regarding claim 14, Neukermans teaches a registration aperture "that mates with and engages a registration pin that projects from the base plate" for connecting the modules (Col.3, lines 18-25).

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neukermans.

Neukermans does not specifically teach the valves to be check valves and a plurality of inlets dedicated to a single liquid containing sections. However, check valves and multiple inlets are routinely used in the art. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed check valves in the modified apparatus of Neukermans, in order to ensure one-directional fluid flow. It would have been also within the ordinary skill of an artisan to have provided additional inlet ports in the pouch for simultaneous infusion of reagents.

### ***Response to Arguments***

11. Applicant's arguments filed on 06/23/2008 have been fully considered but they are not persuasive, or moot in view of new grounds of rejection.

Applicant argues that, in contrast to Applicants' claimed invention, " Neukermans does not teach or suggest, among other features, a liquid introducing section of a first unit and a liquid leading out section of a second unit being connected such that the micro-volume of liquid is transferred from the second unit to the first unit, with each liquid leading out section having energy application means for applying energy for ejecting the liquid"; that "in Neukermans, the piezoelectric actuators act only as a valve for regulating the flow of liquid in the individual capillaries (by moving the respective blade"; and that "Neukermans provide no liquid transfer between the individual units".

Examiner disagrees with these arguments. First, Neukermans does disclose the outlet ['liquid leading out section'] of one ['second'] component 128 being fluidically connected to the liquid introducing section of another ['first'] component 128, the two

components being configured for transferring micro-volumes of liquid from one to the other by means of piezoelectric actuators (see the discussion above). Second, even acting "only as a valve", the piezoelectric actuators do read on the "energy application means for applying energy for ejecting" liquids". Finally, the serially connected components 128, as shown in Figure 10, do provide liquid transfer between the individual components/ units / modules.

### ***Conclusion***

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalia Levkovich whose telephone number is 571-272-2462.

The examiner can normally be reached on Mon-Fri, 2 p.m.-10 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jill Warden/  
Supervisory Patent Examiner, Art Unit 1797